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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,149	11/01/2000	William F. Swain	APF 34.20	4573

22428 7590 06/15/2005

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EXAMINER	
LI, BAO Q	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/705,149	SWAIN ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-17,19-26 and 28-34* is/are pending in the application.

4a) Of the above claim(s) *1-14 and 35-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-17,19-26 and 28-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03/24/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.D.

DETAILED ACTION

Response to Amendment

1. This is a response to the amendment filed 03/24/05. Claims 15, 17, 26, 28, 30, have been amended. Claims 18 and 27 have been canceled. Claims 1-17, 19-26 and 28-51 are pending. Claims 15-17, 19-26 and 28-34 are considered before the examiner.

2. Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 15-20, 22-29, and 31-34 are still rejected under 35 U.S.C. 103(a) as being unpatentable over Suter et al. (Vaccine 1999, Vol. 96, No. 22, pp. 12697-13702) in view of Hilliard et al. (Arch Virol. 1989, Vol. 109, No. 1-2, pp. 83-102).

5. Applicants traverse the rejection and asserted that claims 15, 17, and 26 now have amended as a vector comprising only certain fragment of a viral gene rather than the whole virus, none of the cited references in the previous office Action teaches or suggests such a genomic fragment of a virus used for immunizing an animal.

6. Applicants' argument has been fully considered; however, it is not found persuasive because the DNA vaccine disclosed by Suter et al. is not the whole virus. In fact, the viral gene cited in the previous Office Action is not a whole HSV virus since it lacks the packaging gene. While it is larger than the 50 kilobases, it would still be obvious for a person with ordinary skill person in the art to use a smaller genomic fragment in the same way as a DAN vaccine like Suter

et all demonstrated to immunize an animal because Suter et al. already approve that a larger genomic fragment of HSV is able to induce an immune response as a DNA vaccine.

7. While Hilliar et al. does not teach the size limitation of HSV, they teach that the HSV 1 and HSV 2 were most closely related to each other in structures and functions. Cross-hybridization between simian and human herpesvirus genomes demonstrated that extensive homology exists between each of the simian viruses and both HSV1 and HSV 2. Therefore, it give a clue that selection of HSV-2 is an obvious choice for the claimed invention.

8. Since applicants does not that it is an non-obvious and an unexpected result for selecting only 5-50 linkobase of HSV genomic fragment rather than a larger piece of HSVgenomic DNA fragment, and which fragment should be removed from the larger piece of the viral genomic DNA, the claimed method is still considered as prima facie obvious absence unexpected results. The rejection is therefore, maintained and then made Final.

New ground rejection.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 15-17, 19-26, 29-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, Applicants only disclose to use a DNA vector as a DNA vaccine for eliciting an immune response, Applicants do not have a possession for more than one vectors to delivery more than one pathogens DNA fragments having at least 80% homology to a virus genomic fragment or a DNA fragment hybridizing to the virus genomic DNA, especially,

the DNA fragments are in size between 5 kilobase to 25 kilobase carried by a regular plasmid DNA or between 25 kilomase to 50 kilobase carried by a cosmid respectively.

11. The first paragraph of 35 U.S.C. requires that the specification shall contain a written description of the invention. This requirement has several objectives: 1). To clearly convey the information that an applicant has invented the subject matter which is claimed; 2). To put the public in possession of what the applicant claims as the invention; and 3). To promote the progress of the useful arts by ensuring that the patentee adequately describe their inventions in their patent specification in exchange for the right to exclude others from participating the invention for the duration of the patent term.

12. Therefore, to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. The possession of claimed invention can be shown by describing the claimed invention with al of its limitation in the specification including drawing or description of an actual reduction to practice. The written description may arise in the following situations: a). The claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention; b). The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art; and c). The invention is described solely in terms of a method of its making coupled with its function and there is no described or art recognized correlation or relationship between the structure of the invention and its function etc.

13. In addition, Vas-Cath. V. Makurkar, 19USPQ2d 111, clearly states "applicant must convey with reasonable clarity to those skilled in the art, as of the filing date that he or she was in possession of the invention. The invention is, for purpose of the 'written description' inquiry, whatever is now claimed." (see page 1117). The specification should "clearly allow person of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). Moreover, to be in the possession of any claimed invention, the applicants must show that a significance of conception and reduction to practice was reached before the application was filed. This concept is further addressed by the court in Fiers v. Sugano where it

was emphasized that "[c]onception is a question of law, reviewed de novo on appeal, and if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, regardless of complexity or simplicity of method of isolation.

14. In the instant case, a). The claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention because applicants only describe to induce an immune response by using HSV glycoprotein B or HSV glycoprotein D carried by a vector respectively, wherein the full length of glycoprotein D is about 1182 base pair and glycoprotein B is about 2110-2121 base pair. Applicants do not describe any big fragment from 5 kilobase to 50 kilobase carried by two vector constructs. b). It is well known in the art that HSV DNA vaccine is made by plasmid DNA encoding glycoproteins gD and/or gB or the immediate-early protein ICP27. However, claims 15, 17 ands 26 fail to define what the part of a virus fragment sized with 5 to 50 kilobases should be used. While the hybridization technique is known in the art, the applicants are reminded that satisfaction of the enablement requirement does not satisfy the written description requirement. See In re Barker, 559 F.2d 588, 591, 194 USPQ 470, 472 (CCPA 1977) (a specification may be sufficient to enable one skilled in the art to make and use the invention, but still fail to comply with the written description requirement). See also In re DiLeone, 436 F.2d 1404, 1405, 168 USPQ 592, 593 (CCPA 1971). Applicants do not teach any other fragment except HSV glycoprotein D or glycoprotein B that is used for constructing a DNA vaccine. For the written description requirement, an applicant's specification must reasonably convey to those skilled in the art that the applicant was in possession of the claimed invention as of the date of invention. Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997); Hyatt v. Boone, 146 F.3d 1348, 1354, 47 USPQ2d 1128, 1132 (Fed. Cir. 1998). Thus, a specification contains sufficient information to enable a skilled chemist to produce a particular compound because it gives detailed information on how to produce analogous compounds, but it makes no reference to the compound in question; the "written description" requirement has not been met even though the claimed subject may be enabled.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li
06/09/2005

James C. Housel 6/13/05
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